PATENT
0147-0229P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant:	ECKERT, Helmut et al.	Conf.:
Appl. No.:	NEW	Group:
Filed:	July 13, 2001	Examiner:
For:	USE OF ANTIBODIES FOR THE VACCINATION AGAINST CANCER	

LETTER SUBMITTING TRANSLATION OF
AMENDMENTS UNDER PCT ARTICLE 34

Assistant Commissioner for Patents
Washington, DC 20231

July 13, 2001

Sir:

Attached herewith is a translation of the amendments to the claims under PCT Article 34 (35 U.S.C. § 371(c)(3)). Please use the amended claims for entry into the United States national phase.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
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LRS/lmt
0147-0229P

Attachment

Annex to IPER

CLAIMS

1. Use of an antibody which is directed against the cellular membrane antigen Ep-CAM for the preparation of a pharmaceutical composition for the prophylactic and/or therapeutic vaccination against cancer.

2. The use of claim 1, wherein the antibody is of animal origin.

3. The use of claim 1 or 2, wherein the antibody is a monoclonal antibody.

4. The use of claim 3, wherein the antibody is a murine monoclonal antibody, wherein the variable region of the heavy chain is the amino acid sequence as shown in SEQ ID NO:1 and wherein the variable region of the light chain is the amino acid sequence as shown in SEQ ID NO:2.

5. The use of any one of claims 1 to 3, wherein the antibody has the same fine specificity of binding as the antibody as defined in claim 4.

6. The use of any one of claims 1 to 5, wherein two or more antibodies which are directed against different epitopes of the membrane antigen are used in combination with each other.

7. The use of any one of claims 1 to 6, wherein the pharmaceutical composition further comprises also at least one vaccine adjuvant.

8. The use of any one of claims 1 to 7, wherein the pharmaceutical composition is suitable for the administration of the antibody at a dosage in the range of 0.01 to 4 mg antibody.

9. The use of any one of claims 1 to 9, wherein the pharmaceutical composition is suitable for the administration by subcutaneous, intradermal or intramuscular injection.

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LETTER SUBMITTING ARTICLE 34
AMENDED CLAIMS

Assistant Commissioner for Patents
Washington, DC 20231

July 13, 2001

Sir:

The PTO is requested to use the amended sheets/claims attached hereto *(which correspond to Article 34 amendments or to claims attached to the International Preliminary Examination Report)* during prosecution of the above-identified national phase PCT application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Patentansprüche

1. Verwendung eines Antikörpers, der gegen das zelluläre Membranantigen Ep-CAM gerichtet ist, zur Herstellung eines Arzneimittels zur prophylaktischen und/oder therapeutischen aktiven Immunisierung gegen Krebs.

2. Verwendung nach Anspruch 1, wobei der Antikörper tierischen Ursprungs ist.

3. Verwendung nach Anspruch 1 oder 2, wobei der Antikörper ein monoclonaler Antikörper ist.

4. Verwendung nach Anspruch 3, wobei der Antikörper ein muriner monoclonaler Antikörper ist, dessen variable Region der schweren Kette die in SEQ ID NO:1 dargestellte Aminosäuresequenz ist und dessen variable Region der leichten Kette die in SEQ ID NO:2 dargestellte Aminosäuresequenz ist.

5. Verwendung nach einem der Ansprüche 1 bis 3, wobei der Antikörper dieselbe Bindungsfeinspezifität wie der in Anspruch 4 definierte Antikörper aufweist.

6. Verwendung nach einem der Ansprüche 1 bis 5, wobei zwei oder mehr Antikörper, die gegen verschiedene Epitope des Membranantigens gerichtet sind, in Kombination verwendet werden.

7. Verwendung nach einem der Ansprüche 1 bis 6, wobei das Arzneimittel weiterhin mindestens noch ein Vakzine-Adjuvans enthält.

8. Verwendung nach einem der Ansprüche 1 bis 7, wobei das Arzneimittel für die Verabreichung des Antikörpers in einer Dosierung im Bereich von 0,01 bis 4 mg Antikörper geeignet ist.

9. Verwendung nach einem der Ansprüche 1 bis 9, wobei das Arzneimittel zur Verabreichung durch subcutane, intradermale oder intramuskuläre Injektionen geeignet ist.

VERIFICATION OF TRANSLATION

RE: INTERNATIONAL APPLICATION NO: PCT/EP00/00174

I, Andrea Weinl, of Maria-Eich-Str. 31, 82166 Gräfelfing, Germany, am the translator of Patent Application No. PCT/EP00/00174 and the amendments filed under Article 34 PCT
and I state that the following is a true translation to the best of my knowledge and belief.

(Signature of Translator) A. Weinl

(Dated) 13/6/01

The following publications show that antibodies to Ep-CAM were per se known and available to those skilled in the art, though none of the publications describe the presently claimed active immunization therapy.

PUBLICATION	DISCLOSES
1. Ross et al	MAbs GA733 and 17-1A detect the same antigen, though perhaps a different epitope.
2. Sears et al (1984)	MAb 17-1A was known and available to those skilled in the art.
3. Sears et al (1985)	Similar to Sears '984
4. Samonigg et al	Antibody 73-3 reacts with same antigen as MAb17-1A.
5. Hayden et al	Antibodies against Ep-CAM could be made by skilled person by genetic engineering techniques.
6. Cirulli et al	Antibody KS1/4 is an anti-Ep-CAM Mab.
7. Strnad e al	Amino acid and DNA sequence of KSA (identical to Ep-CAM) was known so one skilled in the art could make anti-Ep-CAM antibodies.
8. Herlyn et al	MAb 17-1A was known and available to those skilled in the art.
9. USP 6,444,207 (Centocor)	MAb 17-1A was know to be used in high doses.